

PATENT  
USSN 10/061,044  
674543-2001.1

### REMARKS

Reconsideration and withdrawal of the rejections of the application and prompt issuance of a Notice of Allowance are respectfully requested in view of the amendments, remarks and attachments herewith, and the matters discussed with Practice Specialist George Elliot during the email correspondence between July 15<sup>th</sup> and 17<sup>th</sup>, 2003, for which he is thanked for the many courtesies extended.

#### **I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 14-15 remain pending. Claims 14 and 15 have been amended, and claims 16 and 17 have been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. No new matter is added.

It is submitted that the claims, as originally presented and as amended herein, are patentably distinct over the art, and that those claims are and were in full compliance with the requirements of 35 U.S.C. 112. The amendments and the remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112. Rather, the amendments and remarks herewith are made simply for clarification and to round out the scope of protection to which Applicant is entitled.

#### **II. THE SECTION 112 REJECTIONS ARE OVERCOME**

Claims 14 and 15 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was allegedly not described in the specification in such a way as to reasonably convey that at the time the application was filed, the inventors had possession of the invention. Furthermore, claims 14, 15 and 17 were rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for allegedly failing to point out and distinctly claim the subject matter which the applicants regard as the invention. The rejections are respectfully traversed and will be addressed simultaneously.

The amendments herein have cancelled dependent claims 16 and 17 and amended claims 14 and 15 to recite "wherein the inhibitor is carbenoxolone or a pharmaceutically acceptable salt thereof." Consequently, claims 14 and 15 have been amended to incorporate the limitations of claims 16 and 17, such that the rejections based on the use of the term "inhibitor" are moot.

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Therefore, reconsideration and withdrawal of the section §112, first and second paragraphs, rejections are respectfully requested.

### III. THE ART REJECTIONS ARE OVERCOME

Claims 14-17 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Stewart et al. (J Steroid biochem. Molec Biol 1990, 40:501-509); and, claims 14-17 were also rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Stewart et al. These rejections will be addressed collectively and are respectfully traversed.

It is respectfully submitted that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. See *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure of the claimed invention. See *Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

The present invention relates to methods for inhibiting reductase activity of 11-Beta-hydroxysteroid dehydrogenase 1 (11-Beta HSD1) in *an animal in need thereof* in adipose tissue of the animal comprising administering to the animal an inhibitor of said reductase activity of 11-Beta HSD1 in an amount effective to so inhibit the reductase activity of 11-Beta HSD1, wherein the inhibitor is carbenoxolone or a pharmaceutically acceptable salt thereof.

Stewart et al. contains no teaching or suggestion of inhibiting 11-Beta HSD1 in an animal in need thereof in adipose tissue, and especially no teaching or suggestion of inhibiting the reductase activity of 11-Beta HSD1 in *an animal in need thereof* in adipose tissue.

Simply, Stewart et al. is silent as to the fact that 11-Beta HSD1 is a reductase in adipose tissue, and that carbenoxolone may be administered to an animal in need thereof to inhibit the reductase activity of 11-Beta HSD1.

Furthermore, Stewart provides no teaching or suggestion of the desirability of the instant invention and no teachings or suggestions as to the activity of 11-Beta HSD1 in adipose tissue.

There is also no teaching or suggestion of the desirability of modifying Stewart to arrive at the instant invention. Thus, the requisite reasonable expectation of success of the instantly claimed invention, as called for by MPEP 2143.02, is not present.

Simply, any prior administration of an inhibitor of 11-Beta HSD1, e.g., carbenoxolone, is insufficient for the PTO to assert that the claimed methods are anticipated or obvious in light of

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the present claims directed towards methods for inhibiting reductase activity of 11-Beta-hydroxysteroid dehydrogenase 1 (11-Beta HSD1) in *an animal in need thereof* in adipose tissue of the animal comprising administering to the animal an inhibitor of said reductase activity of 11-Beta HSD1 in an amount effective to so inhibit the reductase activity of 11-Beta HSD1, wherein the inhibitor is carbenoxolone or a pharmaceutically acceptable salt thereof.

Therefore, reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 102 and 103 are respectfully requested.

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### REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner and Practice Specialist George Elliot; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

### CONCLUSION

In view of the amendments and remarks and attachments herewith, Applicants have addressed and overcome all of rejections of the application set forth in the Office Action, and the present application is in condition for allowance.

Thus, early and favorable reconsideration and withdrawal of the rejections of the application as set forth in the Office Action, and, prompt issuance of a Notice of Allowance of claims 14-15, or an interview with supervisory review, i.e., an interview including Practice Specialist George Elliot, at an early date, with a view towards reaching agreement on allowable subject matter, are earnestly solicited.

Respectfully submitted,

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**ABSTRACT**

This invention relates to the interconversion of inactive 11-keto steroids with their active 11B-hydroxy equivalents, to methods by which the conversion of the inactive to the active form may be controlled, and to useful therapeutic effects which may be obtained as a result of such control. More specifically, but not exclusively, the invention is concerned with interconversion between cortisone and cortisol in humans.